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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/571,018	03/08/2006	Mikio Shoji	023312-0122	4736

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EXAMINER	
EMCH, GREGORY S	

ART UNIT	PAPER NUMBER
1649	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/571,018	SHOJI ET AL.	
	Examiner	Art Unit	
	Gregory S. Emch	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 November 2008 and 10 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-43* is/are pending in the application.

4a) Of the above claim(s) *43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/08/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 23-42 in the reply filed on 10 July 2008 is acknowledged.

Applicant's election of the species of SEQ ID NO: 5 in the reply filed on 10 July 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant's election of Alzheimer's disease in the reply filed on 20 November 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim 43 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the replies filed on 10 July 2008 and 20 November 2008.

Information Disclosure Statement

A signed and initialed copy of the IDS paper filed 08 March 2006 is enclosed in this action.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

All of the claims under examination require the use of a monoclonal antibody which specifically reacts with a derivative of a partial peptide at C-terminal region of a β-amyloid. Several examples of derivatives of β-amyloids are described at p.7, lines 10-29 of the specification, but the list is exemplary and not limiting. Here, it is also taught that "β-amyloids or derivatives thereof can be prepared, for example, from mammals such as humans, monkeys, rats, mice, etc." However, this portion of the specification does not describe which amino acid residues are present in the entire genus of antigens, i.e. β-amyloid derivatives that are encompassed by the claims. Although the specification provides a few examples of peptide antigens and provides actual reduction to practice of an antibody raised to a mouse antigen (Example 1, pp.22-24), it fails to disclose the structures common to all members of the genus of proteins encompassed by the broad definition of "derivatives of β-amyloids." In the absence of a known or

disclosed correlation between structure and function, claims which encompass antibodies with an undefined antigen are generally not considered described. Applicants are directed to the recently-published guidelines on interpretation of the written description requirement, available on the internet at: http://www.uspto.gov/web/menu/written.pdf . See in particular Example 14, p.49, drawn to antibodies to a genus of proteins. Since the specification does not disclose the structural features shared by all of the antigens encompassed by claims including those from other species and since there is no disclosure of a correlation between structure and function that would allow those of skill in the art to recognize other members of the claimed genus from the disclosure of the murine antigen, there is no evidence that the murine antigen is representative of the genus of antigens from other species. Thus, the claims do not meet the written description requirement.

Claims 23-42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for treating Alzheimer's disease and associated diseases comprising administration of the claimed antibody, does not reasonably provide enablement for a method for preventing Alzheimer's disease and associated diseases comprising administration of the claimed antibody. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and, (8) the breadth of the claims. *In re Wands*, 8 USPQ2d, 1400 (CAFC 1988).

Practicing the instant invention to "prevent" Alzheimer's disease and associated diseases would require undue experimentation. Prevention requires 100% efficacy. That is, no patient treated with the active agent develops the disease. The speciation discloses no guidance or working examples of using an antibody as claimed to provide complete prevention. Thus, there are no working examples commensurate in scope with the claims. The art does not provide compensatory teachings as it is silent with respect to preventing Alzheimer's disease and associated diseases. Conversely, the art indicates that there is no known cure, treatment or preventative measure for Alzheimer's disease and related diseases, as evidenced by Vickers (Drugs Aging. 2002; 19(7): 487-94) who teaches, "Alzheimer's disease (AD) is the leading cause of age-related dementia and is set to markedly increase in incidence with the gradual aging of the populations in both developed and developing nations. Along with most brain diseases and conditions, there is no effective treatment currently available to reverse, slow down or prevent its course." Thus, although the specification prophetically considers and discloses general methodologies of using the claimed methods for prevention, the

disclosure is not considered fully enabling of the claims, since the state of the art teaches that prevention of Alzheimer's disease with any agent is not possible.

The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without such guidance, the changes which can be made and still maintain activity/utility is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See Ex parte Forman, 230 USPQ 546 (Bd. Pat. App. & Int. 1986).

Given the breadth of the claims, which includes "preventing" disease, the state of the art which recognizes such complete prevention is impossible, and the lack of working examples and guidance commensurate with the scope of the claims, the large degree of experimentation required in order to accomplish the methods would be undue.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 23, 24, 26, 27, 29, 30, 32, 36, 37 and 39-41 are rejected under 35 U.S.C. 102(b) as being anticipated by 5,750,349 to Suzuki et al. (issued 12 May 1998; citation A1 from Applicants' IDS dated 08 March 2006).

The claims are drawn to a method for preventing and/or treating Alzheimer's disease, mild cognitive impairment or cerebral amyloid angiopathy, which comprises administering to a mammal an effective dose of a monoclonal antibody, which specifically reacts with a partial peptide at the C-terminal region of a β-amyloid or a derivative thereof and does not recognize a partial peptide having the amino acid sequence represented by SEQ ID NO: 8.

U.S. Patent No. 5,750,349 to Suzuki et al. teaches using the C-terminal peptide β-amyloid (35-43) as an immunogen to raise antibodies and teaches that a monoclonal antibody specific for this peptide does not cross-react with Aβ1-40, and thus would not cross-react with a partial peptide having the sequence of SEQ ID NO: 8 (i.e. residues 25-35 of Aβ) or a peptide having the sequence of SEQ ID NO: 7 (i.e. residues 1-28 of Aβ) (col.3, line 66 – col.4, line 27). The patent teaches that these antibodies are useful as compositions for the prevention and treatment of Alzheimer's disease (abstract), thus meeting the limitations of claims 23, 24, 26, 27, 29, 30 and 32. It is noted that the limitations of claims 36 and 37 recite properties or effects of the antibodies upon administration to humans which are inherent to the antibodies. Similarly, claims 39, 40 and 41 recite properties inherent to the administered antibody. Since the patent teaches the active method steps of independent claim 23, the limitations of claims 36, 37 and 39-41 are taught.

Since the patent teaches all the limitations of the claims, claims 23, 24, 26, 27, 29, 30, 32, 36, 37 and 39-41 are anticipated by Suzuki et al.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory S. Emch whose telephone number is (571) 272-8149. The examiner can normally be reached 9:00 am - 5:30 pm EST (M-F).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey J. Stucker can be reached at (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/G.E./

Gregory S. Emch
Patent Examiner
Art Unit 1649
16 March 2009

/Jeffrey Stucker/
Supervisory Patent Examiner, Art Unit 1649